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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,362	04/01/2004	Ferenc Korodi	11128/47602	8238
7590 08/03/2005				
KENYON & KENYON One Broadway New York, NY 10004-1050			EXAMINER DENTZ, BERNARD I	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/815,362

Applicant(s)

KORODI ET AL.

Examiner

Bernard Dentz

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-73 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-10, drawn to an "amorphous simvastatin Ca salt" product, classified in class 560, subclass 228.
- II. Claims 11-31, 70, 71 and 73, drawn to process of making "sim" Ca salt and product by process, classified in class 560, subclass 228
- III. Claims 32-55, 70, 71 and 73, drawn to another process of making sim Ca salt and product by process, classified in class 560, subclass 228.
- IV. Claims 56-62, 70, 71 and 73, drawn to another patentably distinct process of making sim Ca salt and product by process, classified in class 560, subclass 228.
- V. Claims 63-69, 70, 71 and 73, drawn to to another patentably distinct process of making sim Ca salt and product by process, classified in class 560, subclass 228.

In each of the above process Groups claim 73 reciting an extra step in which the salt is converted to sim lactone is included.

Claim 72 is not grouped because it is an improper process claim. It depends from a product-by-process claim which is construed as being drawn to the product of the recited process. Therefore process claim 72 which adds a step to said product by process is improper.

The inventions are distinct, each from the other because:

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In the instant case it is clear that the compound can be made by more than 1 process. See the instant quite different patentably distinct processes used to make it. The processes are patentably distinct. Note that the first 2 start with salts of sim while the other 2 start with sim lactone. Note Gp. II differs markedly from I. in that an acid is added to the inorganic phase before the Ca compound is added. Note that IV. differs from V. in that in the former sim lactone is combined with a mixture of water and a water-miscible solvent while in the latter it is mixed only with water.

Thus each of the above inventions is distinct and independent. To search for all in this crowded, very active art would be very burdensome and not in the interests of effective examination.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Dentz whose telephone number is 571-272-0683. The examiner can normally be reached on Mon-Fri from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dentz

7-26-2005



BERNARD DENTZ  
PRIMARY EXAMINER  
GROUP 16.2